

**SUMMARY OF THE
ENVIRONMENTAL LABORATORY ACCREDITATION BOARD MEETING
JUNE 30, 1999**

The Environmental Laboratory Accreditation Board (ELAB) met on Wednesday, June 30, 1999, at 1 p.m. Eastern Daylight Time (EDT) during the Fifth NELAC Annual Meeting in Saratoga Springs, NY. The meeting was led by its co-chairs, Dr. J. Wilson Hershey of Lancaster Laboratories, Inc. and Ms. Ramona Trovato of the U.S. Environmental Protection Agency (EPA). A list of action items is given in Attachment A. A list of participants is given in Attachment B. The agenda for the meeting is included in Attachment C.

INTRODUCTION

The meeting was called to order by Ms. Elizabeth Dutrow of the United States Environmental Protection Agency (USEPA). Ms. Dutrow reviewed the meeting's ground rules and explained her role as the Board's Designated Federal Officer (DFO). She then introduced Dr. Hershey and Ms. Trovato, who welcomed attendees, reviewed the meeting agenda, and made brief opening remarks. Dr. Hershey explained that ELAB is a USEPA-sponsored advisory committee established under the Federal Advisory Committee Act (FACA). Its members are appointed for two-year terms and may serve no longer than six years. Ms. Trovato announced that ELAB's charter had been renewed. The renewed charter no longer requires that a federal employee be included on ELAB. Ms. Trovato addressed concerns regarding USEPA support of NELAC. She assured attendees that NELAC has complete agency support all the way up to the Deputy Administrator and noted that funds have been allocated for NELAC in the fiscal year 2000 budget.

DISCUSSION OF PROPOSED CHANGES TO NELAC STANDARDS

Chapter Two - Proficiency Testing It was agreed that proficiency testing (PT) is a core element of NELAC and NELAP. Mr. Jerry Parr noted that he had been unable to attend the NELAC PT Committee meeting and asked ELAB members to update him on any resolution of PT provider status and expansion into solid waste and expanded water analytes. Moderate discussion of these issues ensued. It was noted that the PT Standard takes a tiered approach to PT provider accreditation and that accreditation is not readily available. The three tiers of provider accreditation are as follows:

- Tier One - PT providers accredited by the National Institute of Standards and Technology (NIST)
- Tier Two - PT providers accredited by a nationally recognized PT provider accreditor, such as American National Standardization Institute/Registrar Accreditation Board (ANSI/RAB)-registered PT providers or their equivalent
- Tier Three - Accrediting Authority-recognized PT providers not recognized under the previous two tiers

Dr. Hershey and Ms. Trovato opened the issue to the floor for further discussion. Dr. Kenneth Jackson, of the New York State Department of Health, noted that New York intends to become a

PT provider. Their concern is that NIST approval will come late (perhaps as late as November 1999) and will be limited to the Water Safety/Water Pollution (WS/WP) suite of analytes. He noted that the NELAC PT Committee approach is to stipulate that if PT samples are currently available, then they must be used. There is no program for solid waste.

The issue of a date certain from which the first class of applicant laboratories may use PT sample results to fulfill initial accreditation requirements was brought to the attention of ELAB members by Dr. Hershey. Ms. Carol Batterton, Chair of the Transition Committee, noted that her committee had conducted a straw poll in their June 28, 1999, meeting. Given a choice of July 1, 1998, January 1, 1999, July 1, 1999, and the date on which Accrediting Authorities are approved, attendees favored January 1, 1999, as the earliest analysis date from which PT sample results may be used. The January 1999 date allows for analysis of three sets of PT samples by July 2000 if laboratories analyze one set every six months. After some discussion of this issue, it was moved, seconded, and approved unanimously that

ELAB recommend that NELAC set January 1, 1999, as the date certain from which applicant laboratories may use PT sample results to fulfill initial accreditation requirements.

Chapter Four - Accreditation Process At the invitation of ELAB members, Ms. Margaret Prevost, Chair of the NELAC Accreditation Process Committee, provided clarification on proposed new language related to mobile laboratories. Ms. Prevost noted that her committee felt compelled to address the issue of mobile laboratories because some of the newly approved Accrediting Authorities already certify them. Consequently, they have proposed definitions for site laboratory, configured mobile laboratory, and auxiliary mobile laboratory. A site laboratory is a fixed-space laboratory such as might be controlled centrally by an organization like the Department of Defense (but its laboratories exist in separate locations). A configured mobile laboratory operates year-round and needs its own separate accreditation. An auxiliary mobile laboratory is an acute-situation mobile laboratory owned by a fixed-space laboratory and required to follow all quality systems requirements identified in Chapter Five of the NELAC Standards. If the auxiliary mobile laboratory performs a subset of analyses for which the parent laboratory is accredited and goes out into the field for a period of not more than 90 days, then it does not need a separate accreditation. If the sum of the times all auxiliary mobile laboratories owned by one parent laboratory are in the field exceeds 90 days, then they must be accredited. Dr. Kavanagh expressed concern over laboratories involved in critical decisions and that these laboratories need appropriate scrutiny.

It was suggested that ELAB invite an accredited mobile laboratory and/or its Accrediting Authority to make an informational presentation on this issue at the December 1999 ELAB meeting. Several agencies were suggested, including the State of California, the Bureau of Alcohol, Tobacco, and Firearms (ATF), and the Federal Bureau of Investigation (FBI). Mr. Parr will gather more information on candidate laboratories and agencies.

Chapter Five - Quality Systems At the invitation of ELAB members, Mr. Joe Slayton, Chair of the NELAC Quality Systems Committee, joined ELAB for discussion of and response to comments on proposed changes to Chapter Five of the NELAC Standards.

- **Section 5.9.4.2** - ELAB suggested that the word “different” be substituted for the phrase “more stringent” in the last sentence of this section in order to avoid the perception that

NELAC is superceding existing law. Mr. Slayton responded that this wording has not been changed. His committee is satisfied that the Standard does state that if quality control requirements are unclear, the default is the regulation or mandated method. The issue was deemed resolved.

- **Section 5.9.4.2.1. (f)** - ELAB suggested that this item include an exception for techniques, such as Inductively Coupled Plasma (ICP) analysis, that do not require bracketing by calibration standards. Mr. Slayton responded that such an exception is not included in the Standard. This was deemed a significant issue in the case of ICP. Mr. Slayton noted that the revised standard allows two points - one at the decision level and the other higher. He referred to the flexibility of the standard. ELAB considered the issue resolved.
- **Section 5.9.4.2.1 (h)** - ELAB suggested language to clarify any interpretation of this section as requiring the analysis of standards at concentrations below the MDL. In response, Mr. Slayton directed their attention to newly proposed language. The issue was deemed resolved.
- **Section 5.9.4.2.2 (b) (formerly 5.9.4.2.2 (c))** - ELAB requested clarification of language regarding calibration verification check concentrations. In response, Mr. Slayton directed their attention to new language constituting renumbered Section 5.9.4.2.2 (b), which offers flexibility for items that involve internal standards. The issue was deemed resolved.
- **Section 5.9.4.2.2 (e) (formerly 5.9.4.2.2 (f))** - In response to ELAB's suggestion that the requirement that a second consecutive calibration check fall within acceptance criteria is too restrictive, Mr. Slayton described his committee's consensus approach of requiring that laboratories pass two consecutive calibration verifications as a reasonable compromise. The issue was deemed resolved.
- **Appendix B (Definitions for Quality Systems)** - In response to ELAB's discussion of the limitations of the definition of batch, Mr. Slayton noted that a global change has been effected by moving all definitions into Chapter One of the Standards. There has been no 24-hour time limit placed on analytical batches. The issue was deemed resolved.
- **Appendices E (Performance Based Measurement System (PBMS)), F (Listing of Procedures), and G (Listing of Records and Documentation)** - Members of ELAB expressed concern that Appendix E might be misinterpreted as the official NELAC PBMS approach. They also expressed the opinion that Appendices E, F, and G should not be included in the Standard because they are for informational purposes only. They referenced similar informational documents that have been detached from the Standard and posted on the NELAC Website, such as the Assessor Training Manual. After discussion of this issue, it was moved, seconded, and approved unanimously that

ELAB recommend to NELAC that any informational material that has not been voted into the Standard through the NELAC voting process not be published in the Standard, but be posted on the NELAC Website.

NELAC RESPONSE TO ELAB RECOMMENDATIONS

At the invitation of ELAB members, Dr. Jackson, NELAC Chair, joined them to present a report on the status of ELAB recommendations to NELAC. The NELAC response to those recommendations and any pursuant ELAB discussion is summarized below:

- **ELAB Recommendation 3 (2/6/97)** - Native American Tribal Nations participation in NELAC

Dr. Jackson indicated that action is incomplete but moving ahead quickly. The NELAC Board of Directors (BoD) is working with the USEPA Office of Indian Affairs in order to address the issue.

- **ELAB Recommendation 4 (2/6/97)** - NELAC national database to include publicly available information describing the functions performed by individual private organizations for State programs

The National Database *ad hoc* Committee will link the database fields of “Accrediting Authority” and “assessor body.” The “assessor body” field will list pertinent functions.

- **ELAB Recommendation 5A (2/6/97)** - Consistent implementation of PBMS

NELAC has done all it can do until USEPA assumes a PBMS position.

- **ELAB Recommendation 5B (2/6/97)** - Training in implementation of PBMS for State laboratory inspectors

The implementation of this recommendation will follow the implementation of Recommendation 5A.

- **ELAB Recommendation 19 (7/28/97)** - Conflict of interest between public and private sector laboratories

NELAC believes that the revision of Section 6.2.2 (d) of the NELAC Standards resolves this issue.

- **ELAB Recommendation 23 (1/16/98)** - Advisory appendix to address the issue of due process for laboratories

The NELAC Accreditation Process Committee does not believe it appropriate to include a detailed procedure for due process because it varies from State to State. The committee will expand the Standard to list and define the key elements of due process and will submit these definitions for inclusion in the NELAC glossary.

- **ELAB Recommendation 28 (7/1/98)** - Accrediting Authority Review Board (AARB) issues

The NELAC BoD is proposing an amendment to the constitution of AARB to meet ELAB’s concerns.

- **ELAB Recommendation 32 (7/1/98)** - On-site assessment checklist recommendations

The NELAC On-site Assessment Committee has presented draft checklists to the Conference, but they consider it premature to develop a checklist to incorporate the needs of PBMS until USEPA has presented a clear definition of PBMS and it

has been adopted into Chapter Five of the NELAC Standards. The On-site Assessment Committee response elicited moderate ELAB discussion. It was noted that the checklists are a quality systems issue rather than a PBMS issue. ELAB encourages a continued quality systems approach to on-site assessment checklists.

- **ELAB Recommendation 35 (1/14/99)** - Outreach to laboratory associations through the NELAC Webpage

Dr. Jackson noted that this is a small laboratories issue more suited to the NELAC Membership and Outreach Committee than to the Regulatory Coordination Committee. Ms. Irene Ronning, Chair of the NELAC Membership and Outreach Committee, noted that some of the specific recommendations made by ELAB on this issue are outside the scope of the Membership and Outreach Committee (generic QA plans, for example). Other outreach items, such as guidelines gleaned directly from the standards, a published State representative roster for information sources, relevant links, etc., are within the scope of the committee's charge and will be addressed. It was also noted that this recommendation would be further addressed in the Small Labs Workgroup update to follow later in the meeting.

- **ELAB Recommendation 38 (1/14/99)** - Definitions of critical terms prior to defining the accreditation process for non-fixed laboratories

The NELAC Accreditation Process Committee has, as a first priority, developed a definition of "mobile laboratory," as discussed earlier. The development of definitions of critical terms is an ongoing issue with the Field Measurements Committee.

- **ELAB Recommendation 40 (1/14/99)** - Time line recommendation

ELAB's time line recommendation (NELAC standards enforceable one year after adoption, first class of laboratories to be accredited under the 1999 Standards) has been adopted by the NELAC BoD and is included in the NELAC Transition Committee's Frequently Asked Questions (FAQ).

- **ELAB Recommendation 41 (12/10/98)** - Continued work on field measurement standards

The NELAC Field Measurements *ad hoc* Committee has drafted a report on sampling problems. They will draft standards for field testing, but will not address sample collection standards at this time.

- **ELAB Recommendation 42 (3/1/99)** - Laboratory inspections performed according to NELAC standards, no separate category for interim accreditation status in national NELAC database

The Transition Committee has prepared a draft policy that incorporates ELAB's recommendations that initial inspections occur after approval of Accrediting Authorities and that does not note "interim" accreditation status prior to July 2001. There was some ELAB discussion of the three-month application window (July-September 1999) for the initial round of accredited laboratories. The issue was opened to the floor for further discussion. It was noted that the approved July

1999 standards would not be available to laboratories on the NELAC Website until approximately one month after the annual meeting, leaving only approximately eight weeks for them to apply.

Commenters also noted a lack of clarity on Accrediting Authority application issues. In response to these comments, ELAB noted that information on the availability of Accrediting Authority applications is available on the NELAC Website. The 90-day window applies only to laboratories that want to be in the first class of accredited laboratories. Applications will be accepted after September 1999, but there is no guarantee that labs applying after September 1999 will be included in the first class. Members of ELAB acknowledged the rationale of the three-month limit as offering the marketing advantage of being among the first accredited laboratories. After a laboratory has applied to an approved Accrediting Authority for accreditation, then the Accrediting Authority must decide the time line for initial inspection and accreditation based on the number of applications it has received. There was some discussion of what would happen if an approved Accrediting Authority could not handle all of its laboratory applications by the deadline. Ms. Jeanne Mourrain, NELAC Director, noted that two options are available in that situation. An applicant laboratory may be asked to apply to a different State. If the laboratory is unwilling to apply to a different State, the time limit may be extended for all States. A commenter requested that application instructions be posted on the NELAC Website with the approved standards.

ELAB recommend to the NELAC BoD that their established policy on implementation for the first class of accredited laboratories shift the application process from 90 days after the close of the annual meeting to 90 days after the NELAC Standards are available on the NELAC Website.

THIRD PARTY ASSESSORS WORKGROUP UPDATE

Ms. Sandra Wroblewski summarized two major issues identified by the ELAB Third Party Assessors Workgroup. She noted that site-visitor training is the most serious issue. It will cost an estimated \$300,000 to \$500,000 to develop training courses. Although it is agreed that site-visitor training is very important, the question arises of whether there is a better, less costly way to develop training courses. The second issue identified by Ms. Wroblewski is that of PBMS, specifically the impact of ISO Draft 17025 on the NELAC Standards. This is an ongoing issue for international recognition. It was noted that ELAB recommendation Number 32 on on-site assessment checklists addresses third party assessor issues. Dr. Hershey suggested that ELAB include the subject of national approval of assessor bodies on its December 1999 meeting agenda and encouraged the submission of written comments prior to the December meeting. His suggestion met with unanimous approval.

A comment from the floor indicated that the words “assessor,” “auditor,” and “inspector” are still used interchangeably in sections of the standards. Members of ELAB responded that it was their belief that a global change to the word “assessor” had already been made. Since the NELAC Executive Secretary is in charge of editorial changes to the standards, they referred comments to that office.

SCOPE OF ACCREDITATION WORKGROUP

Dr. William Kavanagh reviewed the draft charter for a proposed Scope of Accreditation Workgroup to be co-chaired by himself and Ms. Marlene Moore of Advanced Systems, Inc. The goal of the workgroup is to provide a consensus recommendation to ELAB on scope of accreditation, including relative priority of elements in the database, for NELAC consideration for implementation. The workgroup proposes to provide this recommendation by reviewing pertinent documents and interviewing stakeholders from laboratories, State agencies, USEPA, and individuals knowledgeable about the topic of scope of accreditation. The workgroup proposes to provide an Interim Report of their findings by September 15, 1999, and a Final Report and Recommendation to ELAB by October 15, 1999. It was motioned, seconded, and approved unanimously that

ELAB approve the Scope of Accreditation Workgroup Charter so that its work can begin.

OPEN FORUM ISSUES

Dr. Hershey and Ms. Trovato enumerated issues that were raised in the ELAB Open Forum on June 28, 1999. Their disposition is summarized as follows:

- Need to rework and clarify language concerning “fraud,” a legal term not applicable until conviction. Suggest including stronger statement in standard against inappropriate laboratory practices and separating this language (“fraud”) from the quality systems chapter. Also suggestion to apply Federal Whistle Blower’s Act to NELAC. (Commenter was concerned about protection of employees who report suspect improprieties.)

The word “fraud” has already been removed from Chapter Five of the standards. A commenter from the floor reiterated the suggestion that language concerning ethics be relocated from Chapter Five to Chapter Four. This was deemed an issue for the December 1999 ELAB meeting agenda. It was motioned, seconded, and approved unanimously that

ELAB recommend to NELAC that analysts and management sign a code of ethics for NELAC operation of laboratories.

- Observation of a small core of people involved in furthering ELAB agenda and suggestion that ELAB include more representative membership.

Ms. Dutrow noted that an announcement has already been published in the Federal Register soliciting new ELAB members. She encouraged self-nominations, noting only that members must be non-State and non-federal employees.

- Need to inform laboratories (especially small labs) about how and where to apply for accreditation, and suggestion that NELAC consider extending initial three-month (July-September) laboratory accreditation application window. (Concern that small labs need longer period to become involved.)

This issue was resolved in discussion of ELAB recommendations to NELAC.

- Suggestion that assessors send checklist to lab prior to audit to minimize time spent in audit.

This is a requirement of the standard.

- Matrix spikes issue -- not effective on a batch basis, inappropriate at a frequency of 10%.

This issue was identified as a serious topic requiring additional discussion and deferred to the next meeting. Mr. Parr indicated that he has already prepared a draft report on the matrix spikes issue as addressed in Chapter Five, Appendix D (Essential Quality Control Requirements). He will send the draft report to members of ELAB.

- Reiteration of need for resource list for small laboratories -- discussed in January 1999 ELAB meeting.

This issue was resolved in discussion of ELAB recommendations to NELAC.

SMALL LABORATORIES ISSUE UPDATE

On behalf of Dr. Gary Kramer, Ms. Patricia Pomerleau presented an update on progress made by the Small Labs Workgroup. She summarized comments received since December 31, 1998, on the issue of small laboratories. The majority of the comments expressed concerns with the effect of NELAC Standards on small laboratories, most notably increased financial burden. Referencing ELAB Recommendation 35 to NELAC, Ms. Pomerleau noted that Dr. Carl Kircher, Chair of the NELAC Regulatory Coordination Committee, had indicated that USEPA does not allow NELAC Website cross-links to laboratory organizations. In discussion of this issue, Ms. Trovato and Ms. Dutrow indicated that they would reexamine the agency's Website policy. It was moved, seconded, and unanimously approved that

ELAB recommend to USEPA that the agency include relevant cross-links on the NELAC Website.

Ms. Pomerleau also noted that the NELAC Membership and Outreach Committee is drafting presentations about NELAC/NELAP that could be made available on the NELAC Website for outreach to small laboratories. When the issue was opened to the floor for discussion, it was noted that not all small laboratories have Internet access. Ms. Ronning responded that the Membership and Outreach Committee has no budget for mailing and, therefore, is utilizing the Website for most of its outreach efforts. Further discussion from the floor noted that in a rule-making process by which a State adopts NELAC into its State regulations, rule-developing workshops are a good forum for small laboratories. The on-site assessment process also provides small laboratories a good forum to ask questions of state assessors. After considerable discussion of these issues, it was moved, seconded, and unanimously approved that

ELAB continue to include small laboratory issues on its agenda at every meeting, send small laboratory comments received since December 31, 1998, to the appropriate NELAC committee chairs, and ask the NELAC Membership and Outreach Committee to continue to explicitly consider small laboratory issues.

It was suggested that ELAB recommend that the NELAC BoD also put the issue on its agenda at every meeting. After some discussion in which it was noted that NELAC committee chairs already have a heavy workload, it was decided that the cover letter to accompany the comments that are forwarded to committee chairs would note that no response from the chairs is necessary.

SAMPLE SHIPMENT UPDATE

Mr. David Friedman, USEPA/EMMC, informed ELAB that a contractor will assemble materials pertaining to sample shipment issues for his review. The work assignment has been forwarded to the contracts office. He indicated that he would be able to present a significant update on progress in addressing the sample shipment issue by the December 1999 ELAB meeting.

CONCLUSION

Since the allotted time for the meeting was drawing to a close, it was decided that Ms. Dutrow will schedule a teleconference for September 1999 to discuss the status of high-priority items remaining among ELAB recommendations. It was moved, seconded, and approved that

ELAB urge NELAC voting members to adopt the proposals presented in the fifth annual voting session.

The meeting was adjourned by Ms. Dutrow.

ACTION ITEMS
ENVIRONMENTAL LABORATORY ACCREDITATION BOARD
JUNE 30, 1999

Item No.	Action	Date to be Completed
1.	ELAB will recommend that NELAC set January 1, 1999, as the date certain from which applicant laboratories may use PT sample results to fulfill initial accreditation requirements.	
2.	Mr. Parr will gather more information on candidate mobile laboratories and/or their Accrediting Authorities to make an informational presentation at the December 1999 ELAB meeting.	
3.	ELAB will recommend to NELAC that any informational material that has not been voted into the Standard through the NELAC voting process not be published in the Standard, but be posted on the NELAC Website.	
4.	ELAB will include third-party assessor issues (national approval of assessor bodies) on its December 1999 meeting agenda.	
5.	ELAB will recommend to the NELAC BoD that their established policy on implementation for the first class of accredited laboratories shift the application process from 90 days after the close of the annual meeting to 90 days after the NELAC Standards are available on the NELAC Website.	
6.	ELAB will approve the Scope of Accreditation Workgroup Charter so that its work can begin.	Completed
7.	ELAB will include the suggestion that language pertaining to ethics be relocated from Chapter Five to Chapter Four of the NELAC Standards on its December 1999 meeting agenda.	
8.	ELAB will recommend to NELAC that analysts and management sign a code of ethics for NELAC operation of laboratories.	
9.	Mr. Parr will provide ELAB members with his draft report on the matrix spikes issue as addressed in Chapter Five, Appendix D (Essential Quality Control Requirements).	

Item No.	Action	Date to be Completed
10.	ELAB will recommend to USEPA that the agency include relevant cross-links on the NELAC Website.	
11.	ELAB will continue to include small laboratory issues on its agenda at every meeting, will send small laboratory comments received since December 31, 1998, to the appropriate NELAC committee chairs, and will ask the NELAC Membership and Outreach Committee to continue to explicitly consider small laboratory issues.	
12.	Ms. Dutrow will schedule an ELAB teleconference for September 1999 to discuss the status of high-priority items remaining among ELAB recommendations.	
13.	ELAB will urge NELAC voting members to adopt the proposals presented in the fifth annual voting session.	Completed

PARTICIPANTS
ENVIRONMENTAL LABORATORY ACCREDITATION BOARD
JUNE 30, 1999

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Environmental Laboratory Advisory Board (ELAB) Meeting

June 30, 1999

1:00 p.m. - 5:00 p.m.

Sheraton Hotel and Conference Center

534 Broadway

Saratoga Springs, New York

AGENDA

Review of Advisory Committee Meeting Rules	Elizabeth Dutrow, Designated Federal Officer
Welcome, Review of Meeting Agenda	Wilson Hershey, Co-Chair Ramona Trovato, Co-Chair
Discussion of Proposed Changes to NELAC Standards	Wilson Hershey
Third Party Assessors Workgroup Update	Sandra Wroblewski
Scope of Accreditation Workgroup	William Kavanagh
Open Forum Issues Identified on 6/28/99	Wilson Hershey
NELAC Response to ELAB Recommendations	Kenneth Jackson Chair, NELAC
Updates for Ongoing Issues:	Wilson Hershey Responsible ELAB Members
*Small Laboratories	
*Sample Shipment	
*Status of ELAB Recommendations	
Action Item Review	Ramona Trovato
Meeting Closure	Elizabeth Dutrow